

08-14-03

PHA 4292 (3167/2Z)
PATENT

1614
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of John P. McKearn et al.

Art Unit 1614

Serial No. 09/857,876

Filed October 5, 2001

Confirmation No. Unknown

For METHOD OF USING A MATRIX METALLOPROTEINASE INHIBITOR AND
RADIATION THERAPY AS COMBINATION THERAPY IN THE TREATMENT OF
NEOPLASIA

August 13, 2003

COMMISSIONER FOR PATENTS
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ALEXANDRIA, VIRGINIA 22313-1450

SIR:

INFORMATION DISCLOSURE STATEMENT

In accordance with 37 C.F.R. 1.97 and 1.98 and MPEP 609, and in compliance with the duty of disclosure set forth in 37 C.F.R. 1.56, applicants submit copies of the references listed on the attached PTO/SB/08A for consideration by the Patent and Trademark Office in the above-entitled application and to be made of record therein.

Please note that Applicants make no representation as to the accuracy or completeness of the translations of the abstracts submitted herewith.

In preparation of this Information Disclosure Statement, Applicants determined that approximately 443 references were cited in the application. This review eliminated any reference that was determined to be irrelevant or merely cumulative. If the Office would like a copy of the eliminated references, they can be provided at the Office's request.

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* A check in the amount of \$180.00 is enclosed to cover the fee specified in 37 CFR §1.17(p) for submission of this Information Disclosure Statement. The Commissioner is hereby authorized to charge any under payment or credit any over payment to Deposit Account No. 19-1345.

* Also enclosed is Applicants' executed Power of Attorney.

Respectfully submitted,

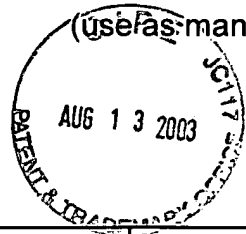


Kathryn J. Doty, Reg. No. 40,593
SENNIGER, POWERS, LEAVITT & ROEDEL
One Metropolitan Square, 16th Floor
St. Louis, Missouri 63102
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KJD/msc
*Enclosures

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PTO/SB/08A INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) 				Complete if Known	
		Application Number	09/857,876		
		Filing Date	October 5, 2001		
		Confirmation Number	Unknown		
		First Named Inventor	John P. McKearn et al.		
		Group Art Unit	1614		
		Examiner Name	Unknown		
Sheet	1	of	4	Attorney Docket No.	PHA 4292 (3167/2Z)

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	
		Number	Kind Code ² (if known)			
	1.	4,140,707		Cleare et al.	02-20-1979	
	2.	5,672,583		Chapman et al.	09-30-1997	
	3.	5,837,696		Golub et al.	11-17-1998	

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T ⁶
		Office	Number ⁴	Kind Code ² (if known)			
/	4.	EP	0 640 594	A1	Fujirebio Inc.	03-01-1995	
/	5.	EP	0 716 086	A1	Boehringer Mannheim GMBH	06-12-1996	
/	6.	EP	0 758 649	A1	Kureha Chemical Industry Co., Ltd.	02-19-1997	
/	7.	EP	0 818 443	A2	American Cyanamid Company	01-14-1998	
/	8.	GB	2 282 598	A	Merck & Co., Inc.	04-12-1995	
/	9.	WO	93/00427	A2	Erziehungsdirektion of the Canton Zurich	01-07-1993	

Examiner Signature		Date Considered	
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¹Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached or place an "A" here if English language abstract is attached..

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Complete if Known

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First Named Inventor	John P. McKearney et al.
Group Art Unit	1614
Examiner Name	Unknown
Attorney Docket No.	PHA 4292 (3167/2Z)

Sheet 2 of 4

/	10.	WO	94/02466	A1	The Du Pont Merck Pharmaceutical Company	02-03-1994	
/	11.	WO	94/21612	A1	Otsuka Pharmaceutical Co., Ltd.	09-29-1994	
/	12.	WO	95/13289	A1	Chiroscience Limited	05-18-1995	
/	13.	WO	95/29892	A1	The Du Pont Merck Pharmaceutical Company	11-09-1995	
/	14.	WO	96/00214	A1	Ciba-Geigy AG	01-04-1996	
/	15.	WO	96/15096	A1	Bayer Corporation	05-23-1996	
/	16.	WO	96/23791	A1	Syntex Inc.	08-08-1996	
/	17.	WO	96/27583	A1	Pfizer Inc.	09-12-1996	
/	18.	WO	97/11693	A1	3-Dimensional Pharmaceuticals, Inc.	04-03-1997	
/	19.	WO	97/19068	A1	Warner-Lambert Company	05-29-1997	
/	20.	WO	97/23459	A1	Warner-Lambert Company	07-03-1997	
/	21.	WO	97/36497	A2	Mars, Incorporated	10-09-1997	
/	22.	WO	97/44315	A1	Warner-Lambert Company	11-27-1997	
✓	23.	WO	97/47599	A1	Fujisawa Pharmaceutical Co., Ltd.	12-18-1997	
/	24.	WO	97/48685	A1	Glaxo Group Limited	12-24-1997	
/	25.	WO	98/03166	A1	Monsanto Company	01-29-1998	
/	26.	WO	98/05635	A1	Chiroscience Limited	02-12-1998	
/	27.	WO	98/08814	A1	The Procter & Gamble Company	03-05-1998	
/	28.	WO	98/08850	A1	The Procter & Gamble Company	03-05-1998	

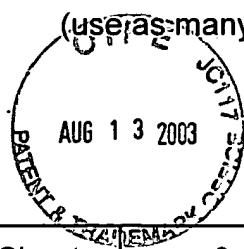
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PTO/SB/08A		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	09/857,876
		Filing Date	October 5, 2000
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		First Named Inventor	John P. McKenna et al.
		Group Art Unit	1614
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Sheet 3 of 4	Attorney Docket No.	PHA 4292 (3167/2Z)	



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	29.	WO	98/15525	A1	Sumitomo Pharmaceuticals Co., Ltd.	04-16-1998	A
	30.	WO	98/22101	A2	G.D. Searle & Co.	05-28-1998	
	31.	WO	98/27069	A1	Fujisawa Pharmaceutical Co., Ltd.	06-25-1998	
	32.	WO	98/33768	A1	Pfizer Products, Inc.	08-06-1998	
	33.	WO	98/33788	A1	Pharmacia & Upjohn S.P.A.	08-06-1998	
	34.	WO	99/21583	A1	Warner-Lambert Company	05-06-1999	

OTHER ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	35.	BROWN, F.K., et al., Matrix Metalloproteinase Inhibitors Containing a (Carboxyalkyl)amino Zinc Ligand: Modification of the P1 and P2' Residues, J. Med. Chem., 1994, pp. 674-688, Vol. 37	
	36.	CHERNEY, R.J., et al., Macrocyclic Amino Carboxylates as Selective MMP-8 Inhibitors, J. Med. Chem., 1998, pp. 1749-1751, Vol. 41	
	37.	DENIS, L.J., et al., Matrix metalloproteinase inhibitors: Present achievements and future prospects, Investigational New Drugs, 1997, pp. 175-185, Vol. 15	
	38.	GALARDY, R.E., et al., Inhibition of Angiogenesis by the Matrix Metalloproteinase Inhibitor N-[2R-2-(Hydroxamidocarbonylmethyl)-4-methylpentanoyl]-L-tryptophan Methylamide, Cancer Research, Sept. 1, 1994, pp. 4715-4718, Vol. 54	
	39.	GEARING, A.J.H., et al., Processing of tumour necrosis factor- α precursor by metalloproteinases, Letters to Nature, Aug. 18, 1994, pp. 555-557, Vol. 370	
	40.	International Search Report for Application No. PCT/US99/30676, dated July 18, 2000	

Examiner Signature		Date Considered	
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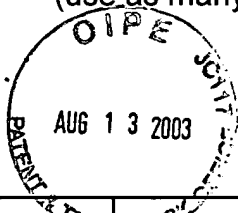
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		Group Art Unit	1614		
Examiner Name	Unknown				
Sheet	4	of	4	Attorney Docket No.	PHA 4292 (3167/2Z)

✓	41.	JACOBSON, I.C., et al., Structure-Based Design and Synthesis of a Series of Hydroxamic Acids with a Quaternary-Hydroxy Group in P1 as Inhibitors of Matrix Metalloproteinases, Bio-Organic & Medicinal Chemistry Letters, 1998, pp. 837-842, Vol. 8	
✓	42.	LARK, M.W., et al., <i>In Vivo</i> Activity of Human Recombinant Tissue Inhibitor of Metalloproteinases (TIMP), Biochem Pharmacol, 1990, pp. 2041-2049, Vol. 39, No. 12	
✓	43.	McGEEHAN, G.M., et al., Regulation of tumor necrosis factor- α processing by a metalloproteinase inhibitor, Letters to Nature, Aug. 18, 1994, pp. 558-561, Vol. 370	
✓	44.	MORIMOTO, Y., et al., KB-R7785, A Novel Matrix Metalloproteinase Inhibitor, Exerts Its Antidiabetic Effect By Inhibiting Tumor Necrosis Factor- α Production, Life Sciences, 1997, pp. 795-803, Vol. 61, No. 8	
✓	45.	NAITO, K., et al., Inhibition of Growth of Human Tumor Cells in Nude Mice by a Metalloproteinase Inhibitor, Int. J. Cancer, 1994, pp. 730-735, Vol. 58	
	46.	PRATT, L.M., et al., Bioorganic Medicinal Chemistry Letters, 1998, pp. 1359-1364, Vol. 8	
	47.	RASMUSSEN, H.S., et al., Matrix Metalloproteinase Inhibition as a Novel Anticancer Strategy: A Review with Special Focus on Batimastat and Marimastat, Pharmacol. Ther., 1997, pp. 69-75, Vol. 75, No. 1	
✓	48.	SOORI, G.S., et al., Phase II Study of Chemo-Biotherapy with Chlorambucil and Alpha Interferon in Patients with Non-Hodgkin's Lymphoma (NHL), Abstract #4032, Blood, 1998, pp. 240b, Vol. 92, No. 10	
✓	49.	THOMAS, C.A., et al., High-Dose Methotrexate (HD-MTX) Monotherapy in Patients with CNS Non-Hodgkin's Lymphoma, Blood, 1998, Abstract #4033, pp. 240b, Vol. 92, No. 10	
	50.	VON ROEDERN, E.G., et al., Design and Synthesis of Malonic Acid-Based Inhibitors of Human Neutrophil Collagenase (MMP8), J. Med. Chem., 1998, pp. 339-345, Vol. 41	
	51.	XUE, C.-B., et al., Design and Synthesis of Cyclic Inhibitors of Matrix Metalloproteinases and TNF- α Production, J. Med. Chem, 1998, pp. 1745-1748, Vol. 41	
	52.	YEH, L.-A., et al., Inhibition of Metalloproteinase by Futoenone Derivatives, Bio-Organic & Medicinal Chemistry Letters, 1995, pp. 1637-1642, Vol. 5, No. 15	

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FEE TRANSMITTAL

Application Number 09/857,876

Art Unit 1614

Filing Date October 5, 2001

Confirmation No. Unknown

Inventor(s) John P. McKearn et al.

Attorney Docket Number PHA 4292 (3167/2Z)

METHOD OF PAYMENT

1. ☐ The Commissioner is hereby authorized to charge the indicated fees to Deposit Account No. 19-1345.
- ☐ The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 to Deposit Account No. 19-1345.
- ☐ Applicant claims small entity status.
- * 2. ☒ Check Enclosed. The Commissioner is hereby authorized to charge any under payment or credit any over payment to Deposit Account No. 19-1345.

FEE CALCULATION

1. ☐ BASIC FILING FEE Subtotal (1) \$ _____
(Type: _____)
2. ☐ EXTRA CLAIM FEES Subtotal (2) \$ _____
Total Claims _____
Independent Claims _____
Multiple Dependent Claims _____
3. ☒ ADDITIONAL FEES Subtotal (3) \$ 180.00
- ☐ Surcharge - late filing fee or oath
☐ Surcharge - late provisional filing fee or cover sheet
☐ Extension for reply within _____ month
☐ Notice of Appeal
☐ Filing a Brief in Support of an appeal
☐ Request for ex parte Reexamination
☐ Petitions to the Commissioner
☒ Submission of Information Disclosure Statement
☐ Recording each patent assignment per property
☐ Request for Continued Examination
☐ Other: _____

TOTAL AMOUNT OF PAYMENT \$ 180.00


Kathryn J. Doty, Reg. (No. 40,593

August 13, 2003
Date

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*Enclosure

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